

REMARKS

Claims 1 and 5-24 are pending, with claims 7-19 and 21 having been withdrawn by the examiner as directed to non-elected subject matter. Claim 1 has been amended to delete “ketoprofen.” Claim 20 has been amended to clarify the term “AUC.” Support for the amendment can be found at least on page 6, lines 30-33 and page 8, lines 17-21 of the specification. Claim 20 has also been amended to clarify that the comparison of AUC is with a non-menthol containing formulation of the same drug. Support for the amendment can be found at least in Examples 3 and 4. No new matter has been added.

Objections to the Claims

Claims 5-6 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims. Applicants thank the Office for indicating that these claims are allowable, and respectfully request that the objections be withdrawn in view of the amendment.

Claim 20 is objected to for allegedly failing to define the acronym “AUC” in its first occurrence in the claims. Applicants have amended claim 20 to define “AUC,” thereby rendering the objection moot.

Claim Rejection – 35 U.S.C. §112, First Paragraph

Claim 22 is rejected under 35 U.S.C. §112, first paragraph, as allegedly failing to comply with the written description requirement. Specifically, the Office contends that the disclosure of an increase of about 10% or more in the average area under the blood or plasma concentration versus time curve as compared to the average AUC for a non-menthol containing formulation fails to provide adequate written support to claim an increase of at least 10% or more for the average AUC for any concentration. Applicants have amended claim 20, from which claim 22 depends, to define AUC as “area under the blood or plasma concentration versus time curve,” thus rendering the rejection moot.

Claim Rejections – 35 U.S.C. §102 over Rubin

Claims 1, 20, and 22-24 are rejected under 35 U.S.C. § 102(b) as allegedly being anticipated by U.S. Patent Application Publication No. 2001/0049363 (“Rubin”). Applicants respectfully traverse.

To advanced prosecution, but without acquiescence to the rejections, Applicants have amended independent claim 1 has been amended to delete the drug ketoprofen. Rubin does not teach or suggest any of the drugs recited in claim 1. Withdrawal of the rejections is therefore requested.

The Office’s admits that the amount of menthol used in the composition of Rubin, i.e. about 0.03 to about 0.06 wt% menthol (see paragraph [0018]), is less than “about 20%” or “about 60%” as recited in the present claims. However, the Office contends that the teaching of 0.03-0.06% is understood to meet the claimed amount of “about 20%” or “about 60%”. Applicants strongly disagree, and point out that such contention is inconsistent with the Office’s statement that the amount of menthol used in the composition of Rubin is less than “about 20%” as instantly claimed (instant claim 1) or “about 60%” as instantly claimed (instant claim 24). As the Office stated, the term “about” permits some tolerance both above and below the recited endpoint. However, one of ordinary skill in the art would not understand “about 20%” to encompass “about 0.03% to about 0.06%,” a range that is more than two orders of magnitudes smaller than “20%”.

Consequently, Rubin does not anticipate the present claims, at least because it does not teach or suggest an effective amount of menthol that is about 20% to about 99% by weight of the composition, as recited in independent claim 1. Accordingly, the rejections of claims 1, 20, and 22-24 should be withdrawn.

CONCLUSION

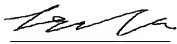
Applicants submit that the claims are allowable. An early and favorable action to that effect is respectfully requested.

The Examiner is invited to contact the undersigned to discuss any issues regarding this response.

In the event that the filing of this paper is deemed not timely, Applicants petition for an appropriate extension of time. The Office is authorized to charge any underpayment or credit any overpayment to Kenyon & Kenyon LLP's Deposit Account No. 11-0600.

Respectfully submitted,
Kenyon & Kenyon LLP

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By: 
Michelle H.W. Shen
Registration No. 48,823

KENYON & KENYON LLP
One Broadway
New York, N.Y. 10004
Tel.: (202) 220-4200
Customer No: **26646**